tries on three continents. Sixty-four invitees finally attended the November 6, 1992 meeting held at the Bascom Palmer Eye Institute. Their studies are summarized in the following pages.

It is hoped that the KPro Study Group will facilitate progress and communication among the world's scientists and clinicians who work to improve the numerous facets of keratoprosthetic implantation. The Group's success will lead not only to a simple, successful procedure, but to an improvement in the overall quality of vision care.

The founding members of the KPro Study Group are grateful to Drs. John G. Clarkson and Edward W.D. Norton for hosting and financing this first meeting, and to Michael T. Gill and Ana Lopez for administrative assistance. Corresponding address: J.-M. Parel, Secretary General, KPro Study Group, P.O. Box 550507, Miami Shores, FL 33153, FAX (305) 326-6139.

Foreword
M.J. Roper-Hall

On November 6, 1992, at the Bascom Palmer Eye Institute in Miami, Fla, a meeting was held of clinicians and basic scientists interested in resolving problems associated with keratoprosthesis (KPro) and their surgical outcome. The meeting was held in response to a question raised in an article published a year before asking why keratoprosthesis were not given more attention.

The principal organizer of the meeting was Jean-Marie Parel, who contacted many scientists and clinicians known to be working in the field. It was expected that about 20 people would attend and that the program would be in the form of a roundtable discussion. However, numbers proved to be larger than expected, with over 100 people expressing an interest, and 64 of those 100 able to attend. Many had been working in isolation, and came from many countries on both sides of the Atlantic.

Thirty papers were presented in four sessions. The topic of the first session was primarily long-term clinical results. It was a surprise to most of those present that there was such a wealth of experience and that many surgeons had used keratoprostheses for several years. Some unexpectedly successful long-term results were presented. Application of the method first introduced by Strampelli seemed to have particular merit.

There was general agreement regarding measures which help in retaining the implant in position with good optical quality. A major disappointment was the frequency of intractable glaucoma, resulting in loss of vision after preliminary success with a keratoprostheses, but a number of ingenious suggestions to overcome this were presented.

The remaining sessions were devoted to biocompatibility and new materials giving prospects for more consistent retention and better clinical results.

The meeting was a great success, with much more promise for the future. We left with the feeling that we had participated in founding a group that will promote development in this field of ophthalmic surgery. It was agreed, with enthusiasm, that the group should continue cooperatively to pursue methods of safer and more effective keratoprostheses. Mr. Parel has accepted the task of planning the next meeting, to be held within 2 years. It may take place in the home town of Pellier de Quengay, who first conceived the idea of an artificial cornea 200 years ago.

REFERENCE

SESSION I
CLINICAL EXPERIENCE I
Chair: E. Lacombe; Moderator: C. Dohlman

Keratoprosthesis: Hopes and Possibilities
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The concept of an artificial cornea, in the treatment of corneal blindness, was suggested by Pellier de Quengay in 1771. Early work with glass, crystal, and celluloid implants took place in the 19th century. After 1906, when the first successful human-to-human corneal graft was performed, there was loss of interest in the keratoprosthesis.

In 1950, Stone and Herbert noticed that polymethylmethacrylate (PMMA) splinters were well tolerated in the cornea of World War II pilots. They showed that large PMMA discs could be retained indefinitely in the cornea of rabbits.

With the introduction of this synthetic plastic polymer of low toxicity and good optical quality, and the failure of keratoplasty in chronically edematous and vascularized corneas, interest in prosthetic corneal implants was renewed.

Intralamellar discs were found to be well tolerated in the human eye, but opacity of the remaining stroma gave poor visual results.

Work then centered on developing a penetrating implant with a buried supporting plate to reduce the tendency to extrusion. Many different materials have been tried. It was hoped that if the implant was buried for long enough it would be sealed off and
could be used to support a penetrating attachment at a second operation.\textsuperscript{9,14}

In 1966, I was invited to attend a foundation meeting, which led to the formation of the International Intracocular Implant Club (IIIC). That meeting was held at The Royal Society of Medicine in London on July 14, 1966. Discussion was divided equally between intraocular lenses (IOLs) and keratoprosthesis. Since that meeting, IOLs have gained paramount interest, although it took about 10 years for wide acceptance. There has been very little further interest in keratoprosthesis in that society.

Technical advances have been made in the manufacture, sterilization, storage, and handling of keratoprosthesis, and in surgical methods.\textsuperscript{15} The use of tectonic grafts (conjunctiva, donor cornea, mucous membrane, etc) and tarsorrhaphy have helped to support and strengthen the host cornea, reducing the number of extrusions.\textsuperscript{16}

The important factors for long-term retention are:
1. The proper selection of cases;
2. Frequent and long-term follow-up examinations;
3. Very prompt attention to any complications;
4. Immediate replacement of collagen by other tissue, if stromal melting occurs; and
5. A healthy lacrimal secretion.

Predicting the future is unsafe, but it is my impression that the material from which the implant is made may be less important than the quality of tissue into which it is placed. Both aspects are discussed in the abstracts presented in this issue of Refractive and Corneal Surgery.

REFERENCES


Keratoprosthesis: 25 Years Experience
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BACKGROUND: The author reports on his experience with 84 cases of optical keratoprosthesis performed since 1967.

MATERIALS AND METHODS: The keratoprosthesis were carried out either by intracorneal anchoring or according to Strampelli as osteo-odontokeratoprosthesis.\textsuperscript{15}

RESULTS: Short-term improvement lasting up to 14 years was achieved in 25% of the eyes, and there was an improvement (up to 14 years) in eight patients. The operation had to be repeated in 30%. The keratoprosthesis (Fig 1) was anchored under a firmly attached flap of oral mucosa transplanted to the cornea after cataract operation. Common complications were glaucoma, hypotony, extrusion of the implant, development of a retroprosthetic membrane, and retinal detachment. Only in cases of severe damage to the cornea after alkali or acid burns, trauma, or pemphigoid and failure of previ-

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meticulous follow-up care are essential prerequisites for success.

REFERENCES

Ceramic Keratoprosthesis
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BACKGROUND: The basic design of this keratoprosthesis consists of an optical cylinder with a power of 60 diopters to correct an aphakic eye and a supporting plate, both made of aluminum oxide ceramic (corundum, Al₂O₃), the colorless version of sapphire or ruby. This keratoprosthesis is no longer manufactured. The material has been shown, in orthopedic and dental implants, to be bioinert. Biocompatibility has been found to be excellent as demonstrated by the adhesion of soft tissue to the implant surface and the growth of osteoplasts to the surface of orthopedic implants. The advantage of having the optical cylinder with a completely biocompatible material would imply that the conjunctival tissue should adhere to the sides of the optical cylinder, thus sealing this portion to the influx of tears or bacteria and also protecting the remaining portion of the implant.

MATERIALS AND METHODS: A polycrystalline Al₂O₃ called Frialit was used to make the retaining ring. It is virtually without pores, has a white appearance, and can be finished with a rough or smooth surface. This opaque retaining ring is 8.5 mm in diameter, has a threaded hole in the center to accommodate a 3.5-millimeter diameter corundum optical cylinder, and has multiple perforations for suturing to the cornea. The optical cylinder is made from a single Al₂O₃ crystal. It is lathed to obtain the required shape. It is 10 mm long with a refractive index of 1.767. The polished surface is extremely hard and is wettable.

Indications include cloudy, vascularized corneas not amenable to transplantation, repeated graft failures, eyes with good color and light perception, an adequate amount of conjunctiva, some tears, and
good eyelid function. Typical candidates have sustained alkali or acid burns.

Contraindications include ocular cicatrical pemphigoid, severe dry eye, advanced glaucoma, and diabetes.

The operative technique has been described in a previous publication.1

RESULTS: Since 1980, 15 through-the-lid keratoprosthesis were implanted and 10 through the cornea and conjunctiva. All through-the-skin implants were extruded within 2 years following surgery. Transconjunctival prosthesis, on the other hand, have been retained from 5 to 8 years and the long-term retention has been better in some cases due to the less severe preoperative condition of the eye, better amount of tear production, and more careful postoperative handling of the operated eye.

CONCLUSIONS: I think that the aluminum oxide ceramic is extremely biocompatible and perhaps the usual graft of periosteum is not necessary since it does not provide any strength to the fixation of the supporting plate. Also, the thread on the prosthesis may not be essential since manipulation of the optical portion tends to break the adhesion of the conjunctiva, which is one of the elements that contributes to long-term retention.

REFERENCES

Twenty-Three Years of Keratoprosthesis Research: Present State of Art
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BACKGROUND: In the past, keratoprosthetic surgery showed a high failure rate, mainly due to the failure of the diseased cornea to permanently incorporate a keratoprosthesis by early cicatricial formation around the implant or through a meshwork skirt. The surgical technical part of the keratoprosthesis-implantation has been improved by anchoring the prosthesis on the scleral equator by means of stainless steel sutures instead of employing corneal fixation. Experience over a period of 23 years has shown the effectiveness of this basic change in surgical technique. This favorable effect is based on the countertraction provided by the sutures against intraocular pressure which tends to extrude the implant before permanent cicatricial fixation has taken place. Furthermore, in contrast to any other suturing material, stainless steel sutures have a 100% biological inertness and, therefore, remain permanently fixed in the sclera.

MATERIALS & METHODS: Watertightness of the corneal implant itself is based on its anticonical shape; the circular constrictive effect of the corneal cicatrix creates a valve function due to the anticonical shape of the keratoprosthesis. No permanent union occurs between the artificial cornea and the corneal tissue itself.

The recently introduced anticonical keratoprosthesis with its broader base facing away from the hool of the keratoprosthesis has several advantages over the previous conical model:
1. A wider visual field;
2. Easier fundoscopy by reducing reflexes from the inner side of the keratoprosthesis; and
3. Easier restoration of intraocular pressure without extrusion of the implant, which in turn facilitates the technique of scleral suturing.

Several improvements in surgical technique have been introduced, such as the replacement of external application by an intralamelar insertion of the implant and the treatment of pressure problems by the insertion of a spiralled seton under the hool of the implant.

The champagne-cork keratoprosthesis (Ophtec BV, Groningen, Holland) is made of PMMA (perspex
CQ—ICI); the diameter of its hood is 6 mm, the diameter of the smallest part of its shaft is 3 mm. The hood has been provided with four stainless steel loops inserted in its rim (Fig 1).

RESULTS: Research on equatorial stainless steel fixed artificial corneas on rabbits and in human subjects ranges over a period of 20 years. My thirty personal cases and 160 cases by Dr Daljit Singh of Amritsar, India, form the basis of the present surgical technique. In my own series, there are only two cases of 20 years of successful implantation with good vision.

CONCLUSION: Clinical success is limited because of the underlying pathology. However, implantation of a keratoprosthesis often is the only possible treatment in these severely damaged eyes.

Results of Champagne Cork Keratoprostheses in 127 Corneal Blind Eyes*

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BACKGROUND: In the “less developed” world, nontransparent corneas represent an important percentage of the “incurable” blind. In the former Soviet Union, stable keratoconus constituted about 31% of the causes of blindness (Barkhash, 1958), and in the whole world, six to nine million people are blind from trachoma alone (Thylefors and Dawson, 1988). A substantial percentage of the 10 million corneal-blind worldwide have light-perception and the eyesight of these blind could be restored if corneal grafts and low cost, preferably “no cost” keratoprostheses would be available. But because of the well-known lack of donor eyes and because payable, simply insertable, effective, and safe keratoprostheses do not yet exist, these cornea-blind with light perception are still regarded as blind beyond any help or hope. Because corneal blindness is endemic in economically poor stratifications with a relatively high population growth, the number of corneal blind will probably double in the next 25 years. Twenty million corneal-blind patients in the year 2015? In economically rich countries, the number of incurable cornea-blind patients is still neglected, due to the availability and the success of corneal grafts, which explains also the relatively little research done on keratoprostheses, to be used in routine surgery, like cataract extraction, under the conditions of economically poor countries—in our case, Amritsar, Punjab, India.

MATERIALS AND METHODS: Three types of keratoprostheses were implanted, one made of clinical quality polymethylmethacrylate (PMMA) with a conical central column, a second one of “seawater resistant” B7-glass, glued with UV-hardening epoxy-lacquer in a window frame (“haptic”) of stainless steel (type 316) with a hollow cylindrical central column, and a third one of Compact Disc 2000 Polycarbonate with an anticonical central column. Such port holes look like mushrooms and are fixed like champagne corks. They were first tested, for function and safety, in rabbit eyes, and made aphakic in the same session. The central column of the keratoprosthesis perforates the center of the cornea through a trephined hole 3 mm in diameter. The hat of the mushroom 6 mm in diameter lies on the cornea and is anchored with two permanent 0.07-millimeter thin soft stainless steel (type 316) wires around the whole eyeball, in two planes perpendicular to each other. In Amritsar, Indu Singh implanted 107 champagne cork keratoprostheses unilaterally in bilaterally cornea-blind patients who were also made aphakic in the same session, because of cataract; 43 PMMA, 29 glass/stainless steel, and 35 polycarbonate.

RESULTS: With PMMA keratoprostheses, no retroprosthetic membrane occurred, one extruded, and two had retinal detachments: together 7% (3/43) complications. Thus, through PMMA keratoprosthesis, 40 out of the 43 (93%) blind could see again. With glass/stainless steel keratoprostheses, there were 5 retroprosthetic membranes, 2 extrusions, and 2 retinal detachments. Three of the five retroprosthetic membranes could be removed with a YAG laser: together 21% (6/29). So, through glass/stainless steel keratoprostheses, 23 out of 29 (79%) blind could see again. If we deal with 72 different patients with the same follow up, then we can apply Fisher’s test. The P-value of the one-sided test is 0.09. At the 5% level, there is no indication that both prostheses are different regarding the restoration of eyesight. Of the 35 polycarbonate keratoprostheses, 27 were placed centrally and 8 paraliminally. Visual acuity results with the longest follow up of 5 months were: 6/18 1 eye; 6/24 1 eye; 6/36 2 eyes; 6/60 3 eyes; finger counting 2 eyes (paralimbal — 1). Twenty patients were happy and could do their household chores (paralimbal — 5); four were not satisfied (1 myopic retina, 2 paraliminally placed, 1 unexplained). Complications included infection (2), retinal detachment (1), and retroprosthetic membrane (2). One big problem emerged: the patients didn’t report for follow-up if they were satisfied!

DISCUSSION: The main characteristic of the champagne cork keratoprosthesis is the fixation to the healthy and stable sclera instead of the diseased cornea, as with all corneal grafts and all other keratoprosthesis models. The keratoprostheses act

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* This study is partly financed by the “spearpoint” program (DST/SO) of the Dutch Ministry for International Development & Cooperation.
as a valve; the scleral fixation keeps the valve on the cornea around the trephined hole, and the pressure in the eye pushes the corneal rim around the trephined hole against the “back” of the “hat” of the "mushroom." The resulting pressure on the interface between the cornea and the keratoprosthesis (instead of the traction on the interface inherent to grafts and all other keratoprosthesis types) prevents: 1) leaking of aqueous humour between keratoprosthesis and cornea; 2) “melting away” of corneal tissue around the keratoprosthesis; 3) epithelial downgrowth, marsupialization and/or fistula-formation; 4) penetration of a superficial infection to the inside of the eye; 5) the need for porous “biomaterial” that functions as a “haptic” for ingrowth by the pathological corneal stroma, and overgrowth by mostly pathological corneal epithelium, for a stable and permanent fixation of the keratoprosthesis in the cornea.

The main problem with glass/stainless steel keratoprostheses, as seen by Indu Singh, was the sticking of mucus between the glass and the stainless steel; dry surfaces appeared only in eyes with defective tear formation. The reasons to make glass keratoprostheses (artificial eyes are preferably made of glass) were that glass is less vulnerable to scratching, more hydrophobic than PMMA, and autoclavable. Serendipitously, the technology for manufacturing polycarbonate lenses for compact disc players helped us. A mould for mass production of polycarbonate (CD 2000) keratoprostheses was made by Philips’ Optics, so that one correcting for the average aphakic eye is now available for $3 (US) apiece.

CONCLUSION: In our view, the pessimism in textbooks and articles about the functional results of keratoprostheses until now cannot be extrapolated to the described sclerally fixated “champagne-cork” keratoprostheses.

A Five-Year Follow-Up of 22 Eyes With a Champagne Cork Keratoprosthesis
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BACKGROUND: In 19 patients, 22 keratoprostheses were implanted by one surgeon (J.G.F.W.) between 1969 and 1990. These 19 patients suffered from severe bilateral corneal diseases listed in the Table.

MATERIALS AND METHODS: A one-piece keratoprosthesis with stainless steel fixation was used; a predecessor of the “champagne-cork” polymethylmethacrylate (PMMA) (Perspex CQ-ICCI) keratoprosthesis. In the period of 1976 to 1990, 42 corneal grafts were performed in chemically-burned eyes by one surgeon (H.J.V.-D.). In both patient groups, the surgeon had to deal with severely damaged anterior segments. An attempt was made to determine the elements for the decision to use either a keratoprosthesis or a corneal graft, on the basis of a long-term follow-up study of the two patient groups. The criteria for success or failure were “no loss of visual acuity” when comparing pre- and postoperative visual acuity of the keratoprosthesis patients, and “a clear graft” for the corneal transplant patients.

RESULTS: The survival of corneal transplants in the 42 chemically burned eyes is better when compared to the success rate of the 22 keratoprostheses (Fig 1). The survival of 18 repeated (third or more) grafts in chemically burned eyes is comparable to
the success rate of the keratoprosthesis (Fig 2).

We compared the visual acuity at 6 months postoperative of both patient groups. In the keratoprosthesis group, 14 eyes had improved visual acuity, 2 eyes were unchanged, and 6 eyes developed no light perception. In the transplanted eyes, 33 showed an improved visual acuity and 9 eyes remained unchanged. A long-term follow-up of both groups (1 to 5 years) showed in the keratoprosthesis group, 5 eyes with improved visual acuity, 5 eyes unchanged, 2 eyes with less visual acuity, and 10 eyes with no light perception. In transplanted eyes, twenty-three demonstrated an improved visual acuity, 16 were unchanged, and 3 eyes had no light perception.

CONCLUSION: For patients with chemically burned corneas, a corneal graft remains the first choice of treatment. However, when the second graft has failed, the possibility of a keratoprosthesis must be considered. For patients generally refused for corneal transplantation such as those with eyes without tear production and/or severely damaged eyelid function, a keratoprosthesis may be the only chance for restoration of the vision.

Central and Paracentral Perforating Keratoprosthesis—An Experience of 200 Cases

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BACKGROUND: The Singh-Worst type keratoprosthesis has been used as a classical keratoprosthesis, i.e., in the center of the diseased cornea, and also as a paralimbal scleral window, with fixation to the sclera in the area of the ciliary body in cases where the diseased cornea is not strong enough to hold the prosthesis.

The basic mechanism of implantation is the same in both applications. The Singh-Worst type keratoprosthesis is shaped like a collar stud, with a larger circular anterior flange (6 mm) and a smaller posterior flange (4.5 mm). The two are connected by a central cylinder, 2 mm long and 3 mm in diameter. The anterior surface of the larger flange bears the convex power. Near the periphery of this flange there are eight holes, spread out evenly, each 0.14 mm in size. A harness suture is fixed to each hole. A corneal needle is attached to the other end of each suture. The design of this keratoprosthesis is similar to the way a champagne cork fits into a bottle, hence it is also known as a champagne cork type of keratoprosthesis.

MATERIALS AND METHODS: For placement of a central corneal keratoprosthesis, the surgical steps include:

1. 360-degree peritomy;
2. Eight 80-micron stainless steel harness sutures passed through the scleral tissue radially;
3. 3-millimeter trephine opening into the center of the cornea;
4. Horizontal extension of this opening;
5. Extraction of the lens;
6. Anterior vitrectomy, if necessary;
7. Posterior flange of the keratoprosthesis slipped in through the trephine opening;
8. The horizontal incisions closed with 50-micron stainless steel sutures to grip the waist of the cornea;
9. The 80-micron harness sutures tied in four pairs and tightened just enough to give a slightly puffed appearance;
10. The intraocular tension adjusted to near normal;
11. Conjunctiva sutured back.

For a paracentral keratoprosthesis:

1. The site for the keratoprosthesis implantation is shifted to the nasal paralimbal region, for implantation in the area of the pars plana;
2. All other steps remain the same;
3. The medial rectus muscle is cut at insertion so the eye diverges and the prosthesis faces forward.

RESULTS: In the central keratoprosthesis group, the visual acuities of the patients ranged from no improvement or hand movements to 20/20 (3 eyes). In some patients, vision was better in the early postoperative period, but the results altered later on by the appearance of a retroprosthetic membrane and uveitis. A 90 degree visual field was charted on automated perimetry in one of the best cases. Our
longest surviving case is a 27-year-old woman operated on 9 years ago, who still has a visual acuity of 20/40.

The best patients in the paracentral keratoprosthesis group have achieved 20/200. They are able to carry on with their daily chores reasonably well.

Postoperative complications included retroprosthetic membrane formation, glaucoma, loosening of the prosthesis, choroidal detachment, retinal detachment, and endophthalmitis. Total extrusion of the prosthesis has never occurred. A loosened prosthesis can be refixed.

CONCLUSION: It is important to note that the keratoprosthesis is not merely a lid. Once implanted, it becomes an integral part of a dynamic system.

Two forces act upon the implanted keratoprosthesis: intraocular pressure (IOP) and the grip of the corneal tissue on the keratoprosthesis. If these two forces are at equilibrium with each other, the keratoprosthesis has the best chance for success. If the IOP is high, or if the cornea is not healthy, the corneal tissue may yield and the prosthesis may extrude. If there is continuous pressure on the healthy cornea, pressure necrosis and extrusion of the keratoprosthesis may also result.

The cornea should act as merely a host to the prosthesis, with minimal participation in preventing its extrusion. A unique feature of the Singh-Worster keratoprosthesis is its dual fixation, ie, local and distant. The distant fixation helps by combating the push of the IOP on the keratoprosthesis, thereby preventing extrusion. Hence, what the cornea must normally do is now shared by the sclera as well. Another aim of dual fixation is to prevent any micromovement of the keratoprosthesis which can lead to necrosis of the tissue.

With this prosthesis, we have achieved improved and more reliable fixation, but in many eyes the accompanying problem of retroprosthetic membrane is still responsible for poor vision, even with good fixation of the keratoprosthesis.

Keratoprosthesis With Tibial Autograft
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BACKGROUND: We began to employ this technique 8 years ago, using a piece from the patient’s tibia for the haptic part of the keratoprosthesis, instead of the tooth and mandible previously used in osteodontokeratoprosthesis.

METHODS: The procedure was performed on single eyes of 51 patients and both eyes of 17 patients—a total of 85 eyes. We used buccal mucosa and a tibial fragment for the autograft, with a PMMA optic cylinder (length, 9 mm; diameter, 4 mm; +26.00 diopters) and a special cement (methyl cyanocrylate).

Surgery was performed in three steps:
1. Preparation of the ocular surface which was covered with thick buccal mucosa from the patient's lower lid, later on covering the keratoprosthesis.
2. Preparation of the haptic part of the keratoprosthesis.
   a) X-rays of the tibia made sure that it was in adequate condition, without areas of osteoporosis or other defects.
   b) Extraction of a circular fragment of 10 mm in diameter and 3 mm in thickness from the upper third of the medial part of the tibia was done, using a punchiform steel fraise with the dacrocystorhinostomy motor and a chisel.
   c) We then polished the piece with a circular diamond fraise and made a 3.5-millimeter central opening into which the optic cylinder (diameter: 3.5 mm in its narrow part and 4 mm in its wider part) was fitted and fixed with a cement that hardens within 2 minutes and did not affect the vitality of the bone.
   d) The finished piece was introduced into a pocket in the lower lid, where it was kept for 3 months to decrease rejection or osseous necrosis and to get the piece covered with soft connective tissue (Fig 1).

![Figure 1: Finished keratoprosthesis cylinder glued into the tibial autograft.](image-url)
3. Implantation of the keratoprosthesis was done if the piece was in satisfactory condition when removed from its pocket after 3 months. We dissected the buccal mucosa and made a 4.5-millimeter trepanation in the center of the cornea, through which we removed the lens, whether clear or not, and into which we fit the keratoprosthesis, suturing it to the cornea with 8-0 Vicryl. When well fixed, it was covered with the buccal mucosa.

RESULTs: From 85 cases, 5 had follow up for over 5 years (Fig 2). Among these, the prosthesis was expelled in seven cases, ie, 15.55%, while results are good in all others.

**Figure 2: Keratoprosthesis in place beneath a layer of buccal mucosa for 5 years, with a visual acuity of 20/50 and Jaeger 1.**

CONCLUSION: The use of a heterotopic autograft offers a better adherence between the keratoprosthesis and the eye, and, therefore, reduces the number of expulsions.

**Osteoodontokeratoprosthesis: Present Experience and Future Prospects**

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BACKGROUND: The first and well established biological haptic for keratoprosthesis made of living human tissue was Strampelli's second technique of osteoonto fixation, used since 1964. The anchoring skirt was composed of dentine, alveolar bone with its ligament, periosteum, and a small amount of surrounding soft tissue. Fixing the polymethylmethacrylate (PMMA) optic cylinder to this skirt with a biocompatible adhesive created an osteoonto acrylic keratoprosthesis.

METHODS: A 4- to 5-millimeter diameter disc of opaque cornea was removed; a total iridectomy and a cryogenic lens extraction, even if it is transparent, were done. The osteoodontokeratoprosthesis was placed with the cylinder in the corneal hole and sutured above the limbus and sclera. The whole was covered with oral mucosa.

Osteoodontokeratoprosthesis is a true heterotopic autograft, totally different from every type of keratoprosthesis whether having biological, biocompatible, or biointegrated haptic.

RESULTS: In the 137 osteoodontokeratoprostheses done by us from 1973 to June 1992, we obtained 91.67% success with visual recovery from 7/10 to 10/10 in 63.6% of eyes. Complications occurred in 25 eyes. Eleven eyes (8.33%) had complications which either could not be treated or in which treatment failed. Of these, four eyes lost light perception and three became phthisical.

Fourteen eyes (10.60%) with complications were treated with a functional visual acuity recovery of from 2/50 to 9/10.

The most frequent complication was glaucoma, not caused by the osteoodontokeratoprostheses operation, but previously present, especially in eyes that had suffered severe burns or undergone repeated surgery either by corneal grafts or for glaucoma. We treated glaucoma with a single or double thread cyclodiastasis. In stubborn cases, we used a personal technique of a small silicone tube with valvular action for antiglaucoma drainage.

COMMENT: With reference to biological haptics, we point out that Temprano, who has a large series of successful osteoodontokeratoprostheses done with Strampelli's original technique, has recently reported a new biological haptic of tibial bone. We think that any bone tissue can never be as hard as dentine, nor does it possess like dentine a metabolism slow enough to maintain a firm durable adherence with the resin of the optic cylinder.

Regarding the basic difference between osteoodontokeratoprosthesis and all other keratoprostheses with biocompatible or biointegrated haptics, some important factors must be remembered. The acrylic cylinder causes an interruption in the conjunctival, oral, or cutaneous epithelium covering the haptic, which is generally the point of least resistance to infection, ulceration, and fistula formation.

Strampelli's histological researches on the osteoonto skirt have been recently confirmed by Ricci and colleagues and by ours in a keratoprosthesis block removed after 25 years of good vision. These histological findings confirm that the oral mucous epithelium is not interrupted, but continuous with the dental alveolar ligament, exactly as in live teeth. Furthermore, in our opinion, biocompatible materials lack immunological defense properties and those of proliferation and repair of living tissues.
These conditions, which always end dramatically, have been found in our 31 cases of Choyce's biocompatible haptic keratoprostheses, in spite of good midterm results. We had 81% success after 5 years and 0.6% after 20 years.

Also in biointegrated keratoprostheses, Caiazz and colleagues have reported failure caused by infection in more than one keratoprosthesis with colonized Dacron felt covered by skin. However, we should mention that in our operations, when skin had to be used, the results were as good as with buccal mucosa.

The improvements we made to Strampelli's original technique have contributed to these results. The most significant are: the joining of two osteoontolaminiae when one is too small, and the use of blood relations' teeth and cyclosporine in toothless patients. We also successfully used Eckardt's prosthesis in detached retina cases, performing vitrectomy with perfluorocarbon gas and silicone tamponade.

CONCLUSION: Strampelli's ingenious technique of osteoontokeratoprosthesis was transformed into one less complex which gives good permanent visual recovery if accurately performed in all its detailed stages.

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Girard Keratoprosthesis With Flexible Skirt: 28 Years Experience
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BACKGROUND AND METHODS: The Girard keratoprosthesis was the first to utilize a flexible skirt for fixation. The author has had 28 years experience with his design of a keratoprosthesis which consists of a 4-millimeter optic and a 10-

Figure 1: Girard keratoprosthesis with flexible Proplast skirt. The nut can be used on the back of the keratoprosthesis in conjunction with a scleral graft, but is unnecessary in most cases.

Figure 2: Eye with blast injuries treated with Girard keratoprosthesis with Proplast skirt.

Table
Visual Results in 139 Eyes Treated With Keratoprosthesis

<table>
<thead>
<tr>
<th>Visual Acuity</th>
<th>No. of Eyes</th>
<th>%</th>
<th>No. of Eyes</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/15 to 20/40</td>
<td>76</td>
<td>54</td>
<td>28</td>
<td>20</td>
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<td>20/50 to 20/200</td>
<td>32</td>
<td>23</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>18/200 to 1/200</td>
<td>24</td>
<td>18</td>
<td>18</td>
<td>13</td>
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<tr>
<td>Light perception</td>
<td>5</td>
<td>4</td>
<td>48</td>
<td>35</td>
</tr>
<tr>
<td>No light perception</td>
<td>2</td>
<td>1</td>
<td>28</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>139</td>
<td>100</td>
<td>139</td>
<td>100</td>
</tr>
</tbody>
</table>

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millimeter flexible skirt. Various materials have been used for the skirt such as nylon, dacron, and Proplast (Fig 1). Fibroblasts grow into the skirt, creating a permanent seal and fixation. A nut-and-bolt design was tried but discarded as unnecessary.

RESULTS: Visual results in 139 eyes treated with the keratoprosthesis (Table) has shown vision of 20/15 to 20/40 in 54% and better than 20/200 in 23% (Fig 2). Due to the high rate of complications, long-term follow up shows that these numbers were reduced to 20% and 12% respectively. Early complications included conjunctival retraction, scleral erosion (48%), and extrusion (9%). These early complications have almost been eliminated by most recent designs and surgical technique. The major complications, at present, are uncontrolled glaucoma (9%) and retinal detachment (19%).

CONCLUSIONS: Keratoprosthesis can be an effective method of visual rehabilitation. While early results can be excellent, long-term results in many eyes show a gradual decrease in success. Complications are frequent and require careful and consistent follow up every 3 months by an ophthalmologist familiar with management of keratoprostheses for the duration of the patient's life.

REFERENCES

Keratoprosthesis: Avoiding Complications
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BACKGROUND: Complications associated with keratoprosthesis surgery can be categorized as intraoperative, immediate postoperative (within the first 2 weeks), intermediate (2 weeks to 12 months), and long term (over 12 months).

METHODS: Based on over 25 years of experience with this surgery, we describe methods utilized in attempting to avoid some of the many complications associated with keratoprosthesis.

INTRAOPERATIVE COMPLICATIONS: Difficult in obtaining adequate hemostasis can be mitigated by utilizing retrobulbar, periorbital, and lid injections of anesthetic agents containing epinephrine even when general anesthesia is utilized. Preserved donor cornea material should be available, and preparations for obtaining periorbital and/or buccal mucous membrane should be in place before initiation of the surgical procedure. Hemorrhage as a result of the total iridectomy can be minimized by grasping the iris at its root and gently disinserting it from the ciliary body in a hand-over-hand fashion. Argon Endolaser photocoagulation can be utilized to prevent bleeding into the vitreous cavity, which will retard restoration of vision.

IMMEDIATE POSTOPERATIVE COMPLICATIONS: Pain, elevated intraocular pressure (IOP), aqueous leak, glaucoma, vitreitis, lid inflammation, and endophthalmitis all may occur. The use of bupivacaine in retrobulbar blocks can significantly diminish postoperative discomfort. In a similar fashion, discomfort at the donor sites for fascia lata or periostal grafts can be reduced when these anesthetic agents are utilized. Pain as a result of IOP can be avoided with prophylactic systemic carbonic anhydrase inhibitors. Meticulous preparation of the lids and ocular surface, flushing the operative site with antibiotics during the course of the procedure, and administration of intravitreal antibiotics all combine to reduce the incidence of postoperative endophthalmitis.

INTERMEDIATE COMPLICATIONS: Persistent elevation of IOP can only be avoided or treated with carbonic anhydrase inhibitors while monitoring the appearance of the optic nerve head. Slippage, dislocation, or extrusion of the prosthesis at this early stage can best be avoided by using nonerodable or nonbiodegradable suture materials and by covering the prosthesis with lid tissue, conjunctive, or buccal mucous membrane for the first several weeks. To prevent extrusion of the prosthesis early, surface ulceration or tissue loss must be treated aggressively.

LONG-TERM COMPLICATIONS: Retroprosthetic membrane can be avoided by appropriate iridectomy and vitrectomy techniques and the use of adequate amounts of antiinflammatory agents in the early postoperative period. Minor lid inflammations or infections such as Hordeum or chalazion must be treated aggressively with compresses, as well as systemic and topical antibiotics, to avoid cellulitis and endophthalmitis. While a diagnosis of retinal detachment may be facilitated by ultrasonography, I have never seen a successful reattachment of the retina in a case of keratoprosthesis. Good hygiene, prophylactic antibiotics, daily cleaning of the optical portion of the prosthesis, and 1% medroxyprogesterone drops can reduce the inci-
idence of surface ulcerations and infections over the long term.

REFERENCES

SESSION II
CLINICAL EXPERIENCE II
Chair: J. Temprano; Moderator: H. Cardona

The Dacron Felt Colonizable Keratoprosthesis
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BACKGROUND: The failure of most keratoprostheses is due to the rigid supporting element simply mechanically anchored to the cornea (sutured and or screwed) and not biologically integrated. The mechanical stress leads to inflammation, necrosis, and to the formation of empty spaces at the implant/eye interface with proliferation of epithelial and connective tissue, encapsulation, and/or extrusion of the device due to the lack of biological and mechanical integration.

Owing to the availability of new materials, many keratoprostheses fixed in different ways to the cornea were developed. The importance of the prosthesis design, particularly of the supporting element, was recognized and studied also in relation to the passage of nutrients into the cornea.

An ideal support must accomplish both mechanical and biological functions, i.e., a reliable fixation of the optical part and induction of a seal of connective tissue to block epithelial ingrowth. This component must be made of a biointegrable and colonizable biomaterial without chemical, biological, or mechanical side effects. Its elastic deformability must be similar to that of ocular tissues to limit mechanical stresses causing inflammation and tissue melting.

MATERIALS AND METHODS: With the aim of obtaining a mechanical anchorage and biointegration in 1979, we developed a keratoprosthesis with a polymethylmethacrylate (PMMA) optical cylinder secured as previously described (international patent pending) to a Dacron fabric supporting element that is soft, pliable, and fully colonizable by a vascularized connective preventing corneal necrosis.